

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

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Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2007/017138

International filing date (day/month/year)
31.07.2007

Priority date (day/month/year)
03.08.2006

International Patent Classification (IPC) or both national classification and IPC
INV. G06F19/00

Applicant
SMITHS MEDICAL MD, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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this opinion

see form
PCT/ISA/210

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/017138

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material:

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material:

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing:

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2007/017138

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-26</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-26</u>
Industrial applicability (IA)	Yes: Claims	<u>1-26</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item V.

1. Reference is made to the following document; the numbering will be adhered to in the rest of the procedure:

D1: WO-A-03053503

Article 6 PCT

2. The application does not meet the requirements of Article 6 PCT, because claims 1 and 9 are not concise, and claims 1-26 are not clear.
 - 2.1 Claims 1 and 9 are independent method claims with coincident subject-matter. The presence of these claims within the same application is therefore considered as an unnecessary proliferation of independent claims (see also the Guidelines, 5.13).
 - 2.2 The term "original pump parameter" and "non-original pump parameter", in claims 1-26, are unclear as they do not have any technical meaning.

For the purpose of the examination, these terms will be respectively interpreted as "setup pump parameter" and "current pump parameter", as can be inferred from the description, see e. g. page 6 line 16-page 7 line 17.

Article 33 PCT

3. The present application does not meet the requirements of Article 33 PCT, because the subject-matter of the independent claims 1,9 and 20 does not involve an inventive step in the sense of Article 33(3) PCT.
 - 3.1 Comparing claim 1 against D1, which represents the closest prior art, D1 discloses

(the references in parentheses applying to this document):

An apparatus for indicating a change in operation of a medical infusion pump, the apparatus comprising:

a memory configured to store (memory, claim 1) an original pump parameter (range of acceptable values, claim 1; see also paragraph 2.2 above) and a non-original pump parameter (measured value, claim 1; see also paragraph 2.2 above);
a monitor (information display 102, fig. 1);
a programmable circuit in electrical communication with the memory and the monitor, the programmable circuit programmed to display on the monitor the non-original pump parameter (page 11 lines 5-14).

The difference between apparatus in claim 1 and the one in D1 may therefore be regarded as the displaying of the original pump parameter, said original pump parameter being displayed juxtaposed to the original pump parameter.

The displaying of further information, said information being displayed juxtaposed to other pieces of information, is a trivial technical procedure of any electronic apparatus.

Furthermore, taking in consideration that the original pump parameter to be displayed is available in the system in D1 (see "memory", claim 1) and the document itself suggest the display of further information (e . g. page 11 lines 13-14), the adding of this feature to the subject-matter in D1 would require no inventive effort to the skilled person.

Therefore, the subject-matter in claim 1 is not inventive (Article 33(3) PCT).

- 3.2 Since the subject-matter of claims 9 and 20 is substantially the same as in claim 1, for the same reasons as stated in paragraph 3.1 above these claims lack an inventive step (Article 33(3) PCT).

**WRITTEN OPINION OF THE
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AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2007/017138

4. The present application does not meet the requirements of Article 33 PCT, because the subject-matter of the dependent claims 2-9,10-19 and 21-26 does not involve an inventive step in the sense of Article 33(3) PCT.
- 4.1 The additional feature of claims 8 and 19 is the highlighting of differences between the current pump parameter and the original pump parameter (see also paragraph 2.2 above).

The problem solved by this feature may therefore be regarded as how to simplify, to a human user, the acknowledging of unusual working conditions.

Thus, the problem, concerning only psychological effects related to the particular way of representing the information, does not have technical character, and therefore, no inventive step can be assessed over the above mentioned claims (Article 33(3) PCT).

- 4.2 The additional features of claims 2-7,10-18 and 21-26 are trivial technical implementative details, which the skilled person would apply to the teachings of D1 without exercise of inventive activities. Therefore, said claims can not be considered as inventive (Article 33(3) PCT).

Pietro Rinelli